



***A*nthrax
*V*accine
*I*mmunization
*P*rogram**

Leader's Briefing



Key Messages

- **Your health & safety are our #1 concerns**
- **Anthrax vaccine is safe and effective**
- **The threat of anthrax is deadly and real**
- **Vaccination offers a layer of protection, in addition to antibiotics and other measures, needed for certain members of the Armed Forces**

History of AVIP

- **Secretary of Defense ordered the AVIP in Dec 97**
- **Vaccinations began in Southwest Asia in Mar 98**
- **Vaccinations began in Korea in Aug 98**
- **Vaccine shortage caused slowdowns in 2000-2001**
- **The AVIP is resuming, now that the supply of FDA-licensed anthrax vaccine has been restored**
- **Status:**
 - **Mar 98 to Mar 02: 2.1 million doses to 525,000 people**
 - **18 human safety studies, plus more underway**
 - **7 reviews by independent panels of civilian physicians, all affirming safety and effectiveness of the vaccine**

Independent Scientific Reviews

- **FDA Panel on Review of Bacterial Vaccines & Toxoids, *Federal Register* 1985; 50: pages 51002-117**
- **Armed Forces Epidemiological Board (AFEB), advising DoD, 1994 to present**
- **Cochrane Collaboration, Oxford, *Vaccine* 1998;16:880-4**
- **Working Group on Civilian Biodefense, *JAMA* 1999; 281: pages 1735-45**
- **CDC's Advisory Committee on Immunization Practices (ACIP) (*MMWR* 2000;49(RR-15): pages 1-20)**
- **Anthrax Vaccine Expert Committee (AVEC), 1998 to present**
- **National Academy of Sciences (IOM), Mar 2002**

AVIP Lessons Learned

- **We must ensure a continuous supply of vaccine**
- **We must educate all stakeholders early: patients, family members, health-care professionals, general public**
- **Our patients perceive the risk-benefit ratio from BW vaccines differently than other “routine” vaccines**
- **A strong foundation of research-based, third-party endorsed, published science is critical to credibility**
- **Health care provider involvement is the key to success**

Background: Anthrax Infections

- **Recognized as an illness for centuries**
- **Spores can survive in soil for decades**
- **Once common where livestock were raised**
- **Animal anthrax controlled using vaccine for livestock**
- **Human infection may result from direct contact with infected animals or animal products or anthrax spores**

Anthrax

- **Anthrax can be loaded into shells, missiles, bombs, and other weapons.**
- **Inhalational anthrax is highly lethal.**
- **Vaccination is critical for your protection.**
- **This vaccination program is required, except for legitimate medical exemptions.**
- **Anthrax vaccine is safe and effective, according to FDA, CDC, and National Academy of Sciences.**

Threat

- **Anthrax: the most likely Biological Warfare agent:**
 - **Relatively easy and cheap to produce**
 - **Can be stored for a long time**
 - **Can be dispersed in air in a variety of ways**
 - **Inhalational anthrax is highly lethal**
 - **Odorless, colorless, tasteless, difficult to detect**
- **Anthrax can cause widespread illness and death among unprotected people.**

Anthrax: Three Disease Types

- **Cutaneous (skin) Anthrax**
 - Most common form; spores enter breaks in skin
 - Responds well to antibiotics
 - 5% to 20% of infected people die without treatment
- **Gastrointestinal Anthrax**
 - Ingestion (e.g., eating undercooked, infected meat)
 - Severe gastrointestinal symptoms
 - 50% of infected people die even with treatment
- **INHALATIONAL ANTHRAX**
 - “Flu-like symptoms” early, rapid deterioration, then death
 - After symptoms occur, almost 100% of unprotected, unvaccinated people die
 - About 50% die even with intensive care

Cutaneous Anthrax

- **Spores enter through a break in the skin**
- **Skin infection begins with a raised bump that resembles a spider bite**
- **Within a few days, the bump will turn into an ulcer with a black area in the center (eschar)**
- **Fever, loss of appetite and headache may develop**
- **Lymph glands may swell**



Gastrointestinal Anthrax

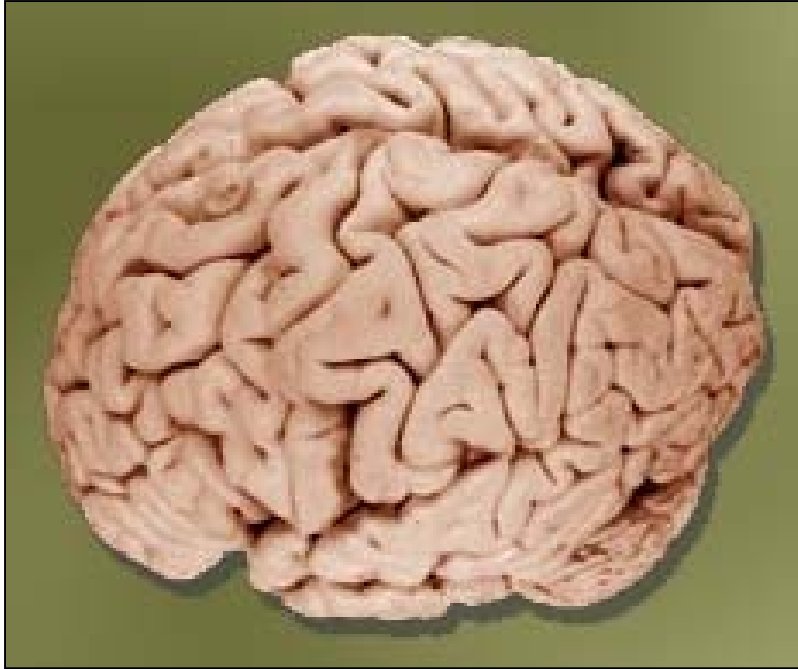


- **Ingestion of undercooked meat from infected animals**
- **Symptoms include nausea, vomiting, fever and severe abdominal pain**
- **50% of infected people die even with treatment**

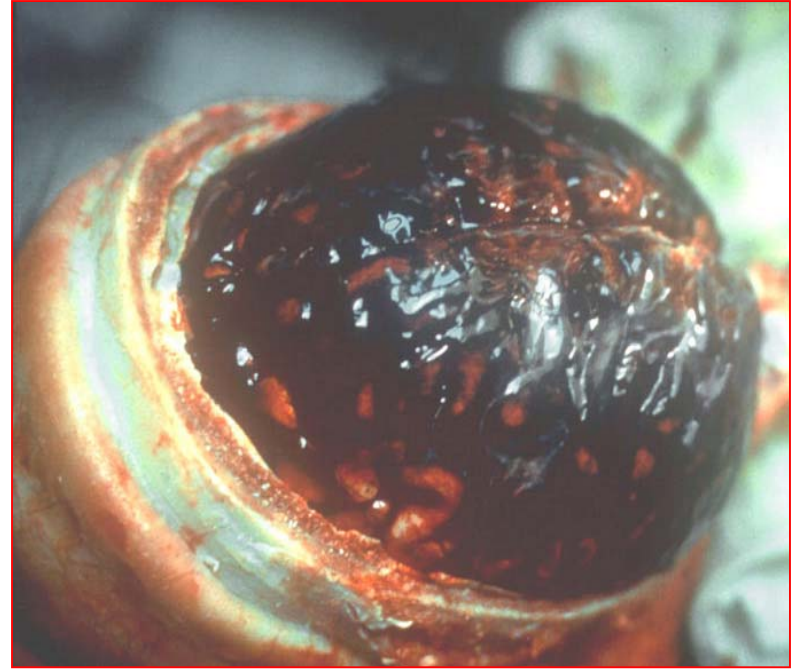
Inhalational Anthrax

- **Inhalational anthrax occurs when spores enter the body through the lungs**
- **Not spread from person to person**
- **Spores migrate to lymph nodes where bacteria multiply and produce lethal toxins**
- **Toxins cause bleeding and destruction of the brain or vital organs in the chest, resulting in death**

The Human Brain



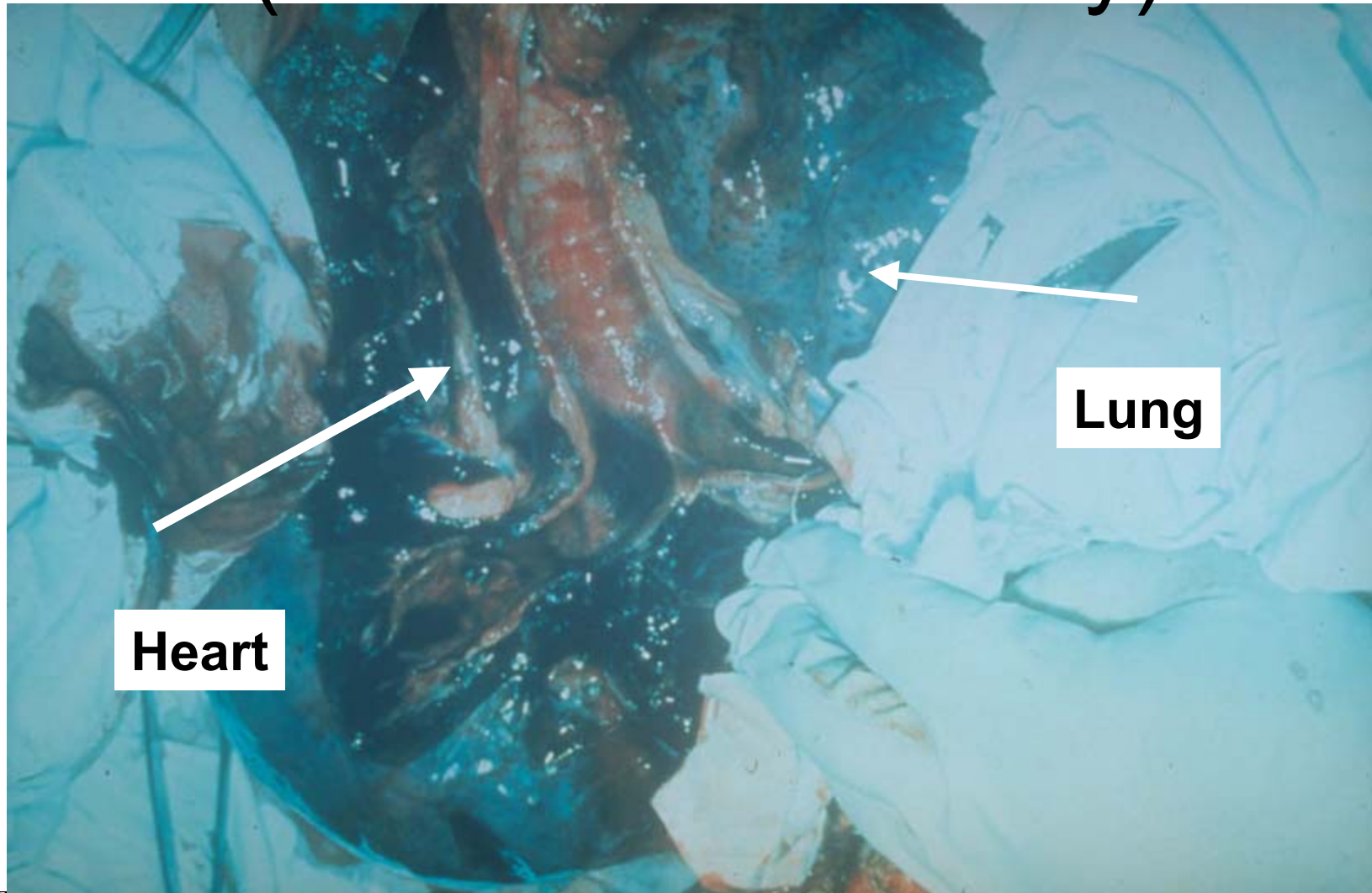
Normal Brain



**Brain of a person who died
from inhalational anthrax**

**Note that the usually clear fluid which surrounds the brain
can become bloody from the anthrax infection.**

Inhalational Anthrax Victim (view of chest cavity)



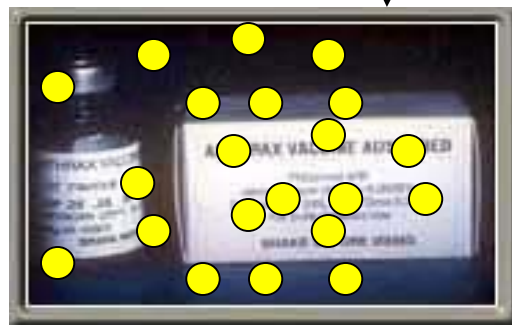
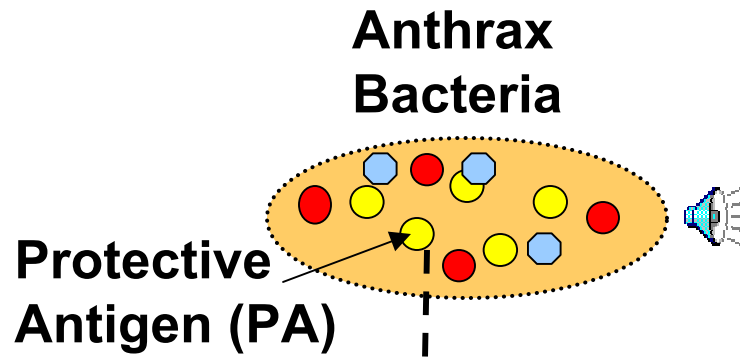
Anthrax Vaccine Facts

- **Vaccine primes body's natural defense system to fight anthrax**
- **Anthrax vaccine cannot cause anthrax**
- **Licensed by the FDA since 1970**
 - **Safely administered in the U.S. to at-risk veterinarians, laboratory workers, and livestock handlers**
 - **2.1 million doses to 525,000 personnel since Mar 98**
- **Manufactured in U.S. by BioPort Corporation**
 - **Lansing, Michigan**

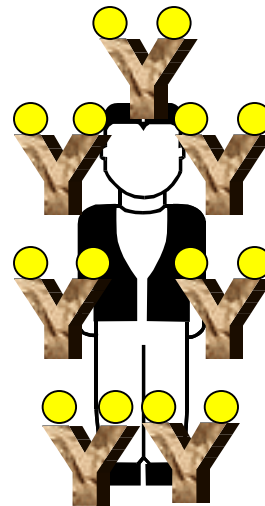
Response to Vaccination

- **Anthrax vaccine, like all other vaccines, stimulates the immune system to produce protective proteins called “antibodies”**
- **Each dose of vaccine adds to protection, like walking up a set of stairs**
- **The full series is needed to obtain maximum and on-going protection.**

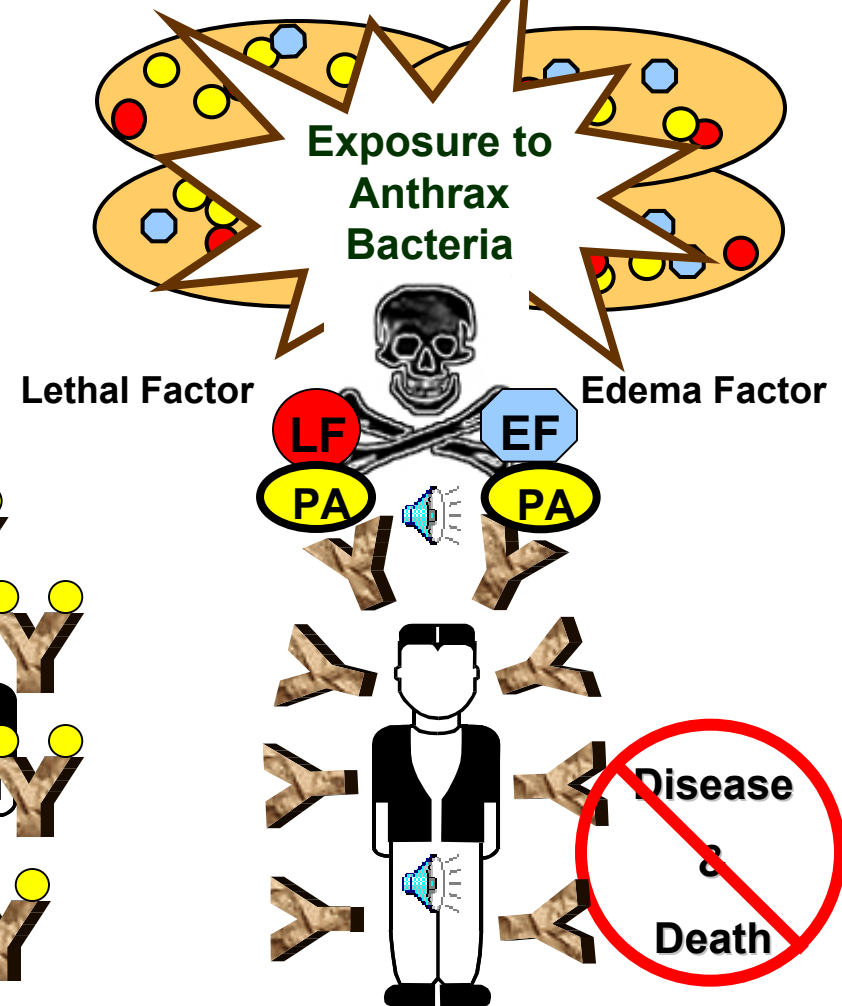
How Anthrax Vaccine Prevents Disease



Vaccine contains PA, extracted from weakened nonlethal anthrax bacteria.



Immune system develops antibodies (Y) to PA, protection from disease.

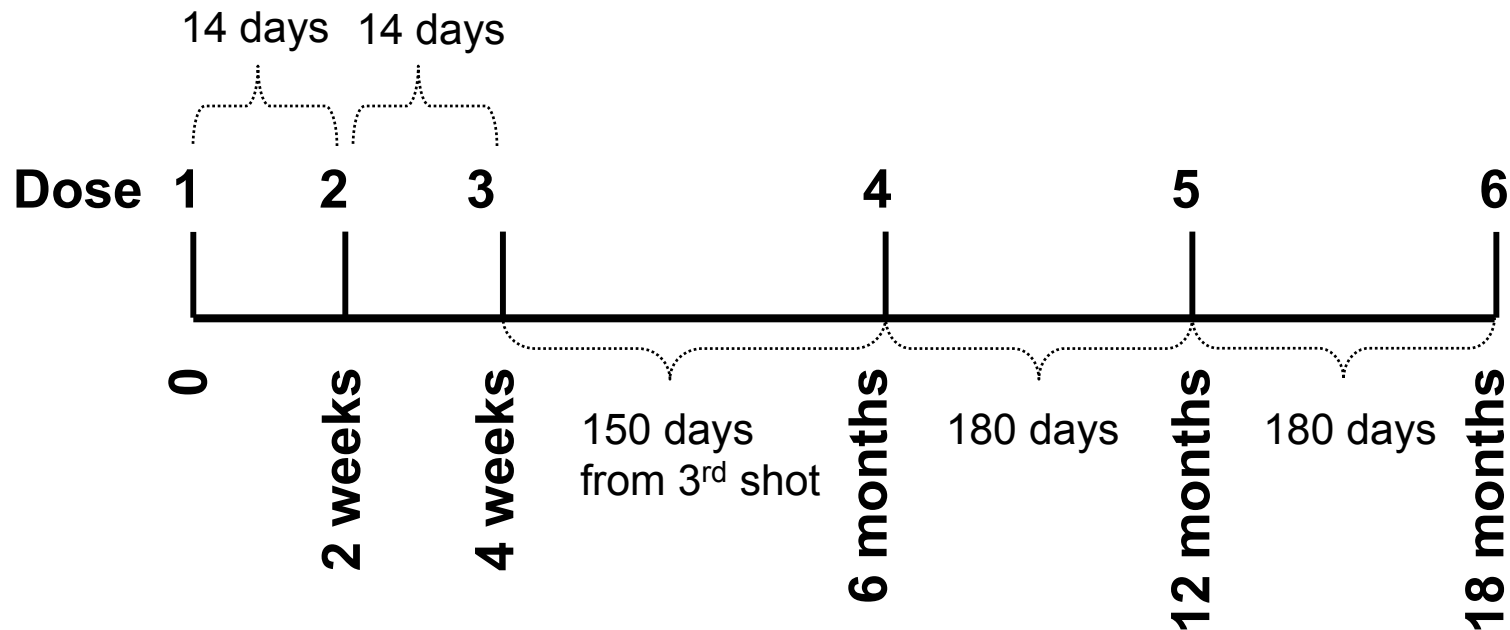


Antibodies “neutralize” PA, common part of anthrax toxins.

Vaccine Protection Against Different Strains

- **Vaccine efficacy demonstrated against numerous anthrax strains (types) in animal studies**
- **Protective antigen is the common disease-causing protein in all anthrax strains**
- **Blocking PA blocks the disease**
- **National Academy of Sciences: “an effective vaccine for the protection of humans against anthrax, including inhalational anthrax, caused by all known or plausible engineered strains”**

Vaccine Schedule



- **Six shots over 18 months, plus annual boosters**
- **Do not compress the schedule**
- **Adjust schedule for individual delays**

Pregnancy

- **Vaccinations routinely deferred during pregnancy**
- **Before vaccination, ask each woman if menses normal and on time. Postpone, if pregnancy possible.**
- **No reason to delay conception after vaccination:**
 - **Anthrax-vaccinated & unvaccinated women at Ft Stewart:**
 - **same rates of conception**
 - **same rates of delivery**
- **Vaccination during pregnancy: Rates of birth defects under study. Rates before & after pregnancy are the same as for unvaccinated women.**
- **Encourage pregnancy testing, if desired.**
- **Details at www.anthrax.mil**

Injection-Site Reactions After Anthrax Vaccination

- For both genders, most injection-site reactions last 1 to 3 days and go away on their own
- From Hawaii, Korea, Ft. Bragg, Ft. Detrick, 1993-2000:
Redness, itching, swelling (lasting a few days)
 - Less than 1 inch: men up to 30%, women up to 60%
 - 1 to 5 inches: 1% to 5%
 - Greater than 5 inches: 1%
 - Swelling may extend below elbow
 - Soreness or local pain in 8% to 19%
 - Lump: 30% to 90% (may persist a few weeks)

Systemic Events

(Events Away from the Injection Site)

- **From 5% to 35% of both genders will notice:**
 - **Muscle aches, joint aches, chills, low-grade fever, no appetite, headaches, nausea, malaise, related symptoms**
 - **Women report these symptoms more often than men**
 - **These symptoms usually go away in a few days, less than a week**
- **Acute allergic reactions occur after any vaccine, about once per 100,000 doses**

Injection-Site Reactions and Systemic Events

- **Consult with your health care provider whether specific medications may help to reduce bothersome symptoms.**
- **Report adverse events after vaccination to health care provider promptly, before additional vaccinations.**

Long-Term Studies

- **Anthrax-Vaccine Recipients Followed for Years**
 - **TAMC-600 Survey (Tripler Army Medical Center)**
 - **Defense Medical Surveillance System (inpatient and outpatient visit surveillance)**
 - **Naval Health Research Center (inpatient and outpatient visit surveillance)**
- **Anthrax-Vaccine Recipients Followed for Decades**
 - **Fort Detrick Multi-Dose, Multi-Vaccine Safety Studies (1940s to 1970s)**
 - **Fort Detrick Special Immunization Program (1970s to present)**

Adverse Event Reporting

- **Vaccine Adverse Event Reporting System (VAERS)**
 - **FDA reviews 100% of adverse-event reports submitted to either FDA or DoD**
 - **Also reviewed by independent panel of civilian physicians**
 - **Anyone can submit a VAERS Form**
- **DoD requires a VAERS Form submission for:**
 - **Loss of duty 24 hours or longer (\geq 1 duty day)**
 - **Hospitalization**
 - **Suspected vaccine vial contamination**
- **Other submissions encouraged**
- **VAERS Form may be obtained from:**
 - **1-800-822-7967 or www.vaers.org**

Reserve Component Adverse-Event Guidance

- **Adverse events after DoD- or USCG-directed vaccinations are line-of-duty conditions.**
- **Someone with an adverse event in a non-duty status possibly associated to any vaccination:**
 - **Seek medical evaluation at a DoD, USCG, or civilian medical treatment facility, if necessary**
 - **Must report the event to your unit commander or designated representative as soon as possible**
 - **See local medical department or squadron for guidance**
- **Commander will determine Line of Duty and/or Notice of Eligibility status, if required**

Access to DoD Military Treatment Facility (MTF)

- **Once designated to receive anthrax vaccine, the following people may receive any dose at any MTF:**
 - **Active component**
 - **Reserve component (Must be in a duty status)**
 - **Emergency essential DoD civilian and contract personnel**
 - **U.S. Coast Guard, as applicable**
- **Mass immunizations require prior coordination with MTF.**

Record Keeping

- **Automated immunization tracking**
 - **Service systems and DEERS central repository**
- **Written entries:**
 - **Health record**
 - **Adult Preventive and Chronic Care Flowsheet (DD form 2766 or DD form 2766C)**
 - **Yellow Shot Card (PHS-731)**
- **Required documentation:**
 - **Date immunized, name of vaccine, manufacturer, lot number, series number, dosage, provider name and MTF address**

What Troops Deserve from Their Leaders

- **Understanding of anthrax as a weapon threat**
- **Understanding that > 525,000 troops have taken the anthrax vaccine before them.**
 - **Q&A page at www.anthrax.mil explains many things of interest to your troops**
- **Planning so they receive their shots on time.**
- **Support so their questions get good-quality answers promptly.**
- **Encouragement to report adverse events after vaccination and get any treatment they need.**

Conclusions

- **Anthrax is a significant threat to our forces**
- **Anthrax vaccine is safe and effective**
- **Personal protective measures are still important**
- **The life-saving benefits of anthrax vaccine make this an essential immunization program**
- **Commanders and unit leaders are key to Service Member understanding of the value of anthrax vaccination**

For Program or General Scientific Information:

- Chain of Command
- AVIP Agency
 - Website: www.anthrax.mil
 - Customized answers to your individual questions via E-Mail: avip@amedd.army.mil
 - Toll-Free: [877.GETVACC](tel:877.GETVACC)
- CDC National Immunization Hotline: [800.232.2522](tel:800.232.2522)
- www.bt.cdc.gov
- www.aviationmedicine.com

For Medical Information:

If a Reserve Component or Active Duty member of the Armed Forces presents at your office for a condition they believe may be an adverse event caused by a vaccination, please provide care appropriate to their condition and contact the following as soon as possible for coordination and payment

- Walter Reed Vaccine Healthcare Center: [202.782.0411](tel:202.782.0411) (website coming soon)
- For information on civilian health-care services outside a Military Treatment Facility, call the Military Medical Support Office, [888.MHS.MMSO](tel:888.MHS.MMSO) ([888.647.6676](tel:888.647.6676)),
<http://mmso.med.navy.mil/>